

ACT 3A AMENDED

CLAIMS

1. Film-shaped therapeutic system (1), comprising at least two layers connected with each other, for transmucosal administration of active substances, which system (1) has a layer (2) which is mucoadhesive in aqueous environment and a mono-layered or multi-layered backing layer (3) prepared on the basis of polyacrylates and serving as active substance reservoir, and wherein at least one of the layers of said system contains active substance, and wherein the said mucoadhesive layer (2) is capable of swelling in aqueous media but is insoluble, or only poorly soluble, therein and contains a polymer mixture comprising at least one hydrophile, mucoadhesive polymer which is embedded or dispersed in a polymer matrix prepared on the basis of polyvinyl alcohol(s).
2. Film-shaped therapeutic system according to claim 1, characterized in that the mucoadhesive layer (2) is substantially made up of the said polymer mixture which is film-forming, capable of swelling in aqueous media but insoluble, or only poorly soluble, therein.
3. Film-shaped therapeutic system according to claim 2, characterized in that the said mucoadhesive polymer(s) is/are selected from the group comprising carboxyl groups-carrying hydrophile adhesive polymers, polyacrylates and their salts, carboxymethyl cellulose and its salts, poly(methyl vinyl ether maleic anhydride) and its aqueous or alcoholic hydrolysates and salts.
4. Film-shaped therapeutic system according to any one of claims 1 to 3, characterized in that the polymer matrix of the mucoadhesive layer has been crosslinked by means of physical or chemical methods.

5. Film-shaped therapeutic system according to any one of the preceding claims, characterized in that the backing layer (3) or - in the case of a multi-layered backing layer - the individual layers (3a, 3b) of the backing layer is/are manufactured on the basis of neutralised polymethyl methacrylates.

6. Film-shaped therapeutic system according to any one of the preceding claims, characterized in that the backing layer, or at least one of the individual layers of the backing layer, contains one or more auxiliary substances, preferably selected from the group of the plasticizers, penetration enhancers, solubilizers, dyes, pigments and matrix formers.

7. Film-shaped therapeutic system according to any one of the preceding claims, characterized in that adjacent layers contain one or more identical or chemically allied base polymers, preferably from the group of the polyacrylates.

8. Film-shaped therapeutic system according to any one of the preceding claims, characterized in that it is made up of 2 to 6 layers, preferably of 2 to 4 layers.

9. Film-shaped therapeutic system according to any one of the preceding claims, characterized in that the backing layer, or that outer layer which is opposite to the mucoadhesive side, forms a boundary layer in which the permeation of water and the diffusion of active substance is reduced, relative to the other layer(s) of the system.

10. Film-shaped therapeutic system according to any one of the preceding claims, characterized in that it is made up of at least three layers and comprises a mucoadhesive layer (2), at least one middle reservoir layer (3a) and an outer

backing layer (3b), with the latter layer forming a boundary layer in which the permeation of water and the diffusion of active substance is reduced, relative to the other layer(s) of the system.

11. Film-shaped therapeutic system according to claim 9 or 10, characterized in that the said boundary layer contains additives which reduce or block the diffusion of the active substance, particularly additives from the group of the pigments and the diffusion-retarding polymers.

12. Film-shaped therapeutic system according to any one of claims 9 to 11, characterized in that the reservoir layer(s) contain(s) one or more additives which increase the swelling capacity and the hydration of the reservoir matrix, said additives preferably being selected from the group of hydrophile, water-binding substances, with polyacohols and polymeric surfactants with an HLB value of ≥ 10 being particularly preferred.

13. Film-shaped therapeutic system according to any one of the preceding claims, characterized in that the active substance(s) is/are present in dissolved, suspended or emulsified form.

14. Film-shaped therapeutic system according to any one of the preceding claims, characterized in that two or more layers contain the same active substance, preferably at different concentrations under formation of a concentration gradient.

15. Film-shaped therapeutic system according to claim 14, characterized in that the individual layers contain additives which cause a modification of the solubility and of the diffusion coefficient of the active substance in the respective layer.

16. Process for medicinal therapy or prophylaxis, wherein an active substance-containing film-shaped therapeutic system according to any one of the preceding claims is applied onto the oral mucosa and is left there for a period of up to 24 h, preferably for a period of up to 6 h.

17. Process according to claim 16, characterized in that the active substance(s) is/are released with an initial burst dose and subsequently with a maintenance dose, the active substance delivery preferably taking place for a period of 0.5 h to 24 h.